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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,715	06/14/2005	Marie-Laure Fardeau	BJS-1721-94	1999

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

KIM, TAEYOON

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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06/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,715

Applicant(s)

FARDEAU ET AL.

Examiner

Taeyoon Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/10/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11 are pending.

Election/Restrictions

Applicant's election without traverse of Group I invention (claims 1-8) in the reply filed on Apr. 5, 2007 is acknowledged.

Claims 9-11 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-8 have been considered on the merits.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claims 1 and 7 disclose the phrase "the *lactigenes* genus". There is no adequate support for the phrase in the specification. It appears that "*lactigenes*" is species of *Exiguobacterium* (genus). Appropriate correction is required.

Claim Objections

Claim 3 discloses a DNA sequence. The sequence is listed without a proper alignment, showing the even numbered lines ending abruptly as if there is missing sequence thereafter. In addition, there is a blank between the sequence. It is not clear whether there is missing sequence in between or it was just simply due to the misalignment. The whole sequence of SEQ ID NO.1 is not necessary to be disclosed in claim, since SEQ ID NO.1 is already disclosed in the claim. Applicant is advised to amend the claim.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 3 discloses the phrase "more than 97% similarity with SEQ ID No.1." There is no adequate description in the specification for the phrase.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel biological materials, specifically *Exiguobacterium lactigenes* under the No. I-2962. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials.

The specification does not disclose a repeatable process to obtain the biological materials, and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited the biological materials (claim 1 and p.2 of the specification), but there is no indication in the specification as to public

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availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit must be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. §1.807) and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit,

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the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information; however, Applicant is cautioned to avoid entry of new matter into the specification by adding any other information.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to ANY bacterial strain having a portion of DNA sequence or at least 70% of genomic DNA sequence capable of hybridizing the DNA of bacterial strain deposited as I-2962, or a bacterial strain having more than 97% similarity with SEQ ID NO. 1. Although the specification discloses a deposited strain of I-2962, there is no description in the specification that a person of ordinary skill in the art would have had possession of the claimed bacterial strains other than I-2962. Furthermore, the phrase "at least 70% of its genome" in claim 2 does not have an adequate support from the specification. The specification only disclose mutants having at least 70% capacity for hybridization with the genomic DNA of the deposited strain, but no disclosure of "70% of its genome" in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The intended scope and meaning of the claimed invention are unclear. Applicant claims any bacteria strain having a DNA sequence hybridizing with the genomic or plasmid DNA of a strain deposited under No. I-2962, but does not set forth the metes and bounds of neither the specific strain intended nor the metes and bounds of the DNA sequence which hybridizes with the DNA of I-2962 in the cited claims. Critical elements of applicant's invention appear to be missing from the cited claim(s) as it would appear that the claims as written would read on ANY strain of *Exiguobacterium* genus that would not appear to be applicant's invention. It is notoriously old and well known in the art of *Exiguobacterium* genus, and they share significant portion of their genomic DNA sequences and thus can hybridize each other. It would appear that applicant's invention requires more than simply the whole genus of *Exiguobacterium* and it would not appear that applicant intended to claim said the entire *Exiguobacterium* genus.

The specification would appear to set forth that applicant's invention requires a specific *Exiguobacterium lactigenes* strain of I-2962, but the cited claims do not specifically point out and distinctly claim this subject matter which applicant regards as the invention.

Therefore, it is unclear what the intended scope of the cited claims is, the claims must be considered indefinite and rejection under the second paragraph of this statute is appropriate.

Claim 1 discloses a bacteria strain having a DNA sequence at least partially hybridizing with the genomic or plasmid DNA of *Exiguobacterium lactigenes* under the No. I-2962. It is vague what would be "at least part of which [the sequence]" as claimed in the current claim. The specification does not disclose what would be "at least part" of the DNA sequence disclosed in the claim.

In addition, it is not clear whether the DNA sequence of the bacteria strain is genomic DNA or a plasmid DNA exogenously introduced or the two bacteria strains are identical. The claim can be interpreted as drawn to any bacteria having a piece of the genomic or plasmid DNA of *Exiguobacterium lactigenes* under the No. I-2962 either endogenously present or exogenously introduced. It appears that the current invention is drawn to a specific bacteria strain deposited as *Exiguobacterium lactigenes* under the No. I-2962, rather than any bacteria comprising at least a piece of DNA sequence from *Exiguobacterium lactigenes* under the No. I-2962. Therefore, it is unclear what the intended scope of the cited claims is, the claims must be considered indefinite and rejection under the second paragraph of this statute is appropriate.

Claims 2-6 recite the limitation "the bacteria strain". It appears that there are two bacteria strains disclosed in claim 1, and it is not clear which bacterial strain the limitation of claims 2-6 intends to point out. For search purpose, the bacteria strain is interpreted as any bacterial strain having similarity with *Exiguobacterium lactigenes* under the No. I-2962.

Claim 3 recites the limitation "the 16S rRNA" in 1st line. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 discloses the phrase "the order of" and it is not clear what the subject matter the phrase intends to point out. The term "order" is considered as the class of scale or magnitude of any amount, and 40 and 50°C is considered as the same order of 2. The expression of "the order of 40 to 50°C" is therefore vague what the phrase intends to point out whether the claim intends to point out the range of temperature being 40 to 50°C or all temperature range having the order of 2. It appears that the temperature being simply in the range of 40 to 50°C. Applicant is advised to amend the claim.

Claims 6 and 7 disclose the term "its DNA" for the content of a G+C being approximately 50 mol%. It is not clear which portion of DNA the claim intends to point out. The G+C content would vary depending on the position of the DNA and without specific positions and length of the sequence, it is not enable to measure the content.

The phrase "these strains" in claim 7 is not clear what the subject matter the phrase intends to point out. The claim disclose a bacterial strain whereas the phrase points out multiple strains which does not have antecedent basis.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter). The standard for

patentability in the area of living organisms and biomolecules is whether the claimed matter "is the result of human intervention." See M.P.E.P. § 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102 (b) as being anticipated by Drancourt et al. (2000; IDS ref.), Farrow et al. (1994; IDS ref.) or Fruhling et al. (2002; IDS ref.) in light of BLAST Basic local alignment search.

Claims 1-7 are drawn to a bacterial strain having a DNA sequence capable of hybridizing with genomic or plasmid DNA of a strain deposited under the No. I-2926 (claim 1); the bacterial strain having at least 70% of its genome being capable of hybridizing with the DNA of the deposited strain (claim 2); a limitation to the bacterial strain having the sequence SEQ ID No.1 or a sequence having more than 97% similarity with SEQ ID No.1 (claim 3); a limitation to the bacterial strain of claim 1 having properties disclosed in claims 4 through 7.

Drancourt et al., Farrow et al. or Fruhling et al. in light of BLAST and NCBI search results disclose a bacterial strain designated as AF227839, X70316.1, or AJ344151, respectively, which has 98%, 97% or 94% of identity with the sequence of AY818050. Since AY818050 is the identical sequence as 16S rRNA sequence of

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Exiguobacterium lactigenes under the No. I-2962, the bacterial strain of Drancourt et al., Farrow et al. or Fruhling et al. anticipates all the limitations disclosed in the current claims. Since AF227839 is identical as the bacterial strain as the claimed invention, the properties disclosed in claims 4 through 7 are considered as inherent properties of the bacterial strain of Drancourt et al., Farrow et al. or Fruhling et al.

M.P.E.P. §2112 states that "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' bacterial strain differs, and if so to what extent, from the bacterial strain discussed in Drancourt et al., Farrow et al. or Fruhling et al. Accordingly, it has been established that the prior art bacterial strain, which meets

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the limitation of the claims, demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed bacterial strain that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known bacterial strain is not disclosed in a reference does not make the known bacterial strain patentable. The new bacterial strain possesses inherent characteristics which might not be displayed in the tests used the reference. Clear evidence that the bacterial strain of the cited prior art do not possess a critical characteristic that is possessed by the claimed bacterial strain, would advance prosecution and might permit allowance of claims to applicants' bacterial strain.

Thus, the reference anticipates the claimed subject matter.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

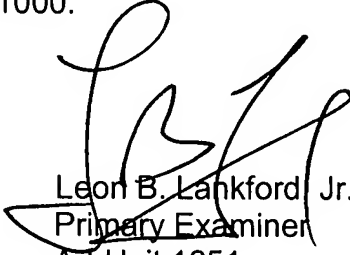
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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim
Assistant Examiner
Art Unit 1651



Leon B. Lankford Jr.
Primary Examiner
Art Unit 1651